

§ 522.1680

albus, *Brucella bronchiseptica*, *Streptococcus spp.*

(2) The drug is administered intramuscularly at a recommended daily dosage to dogs at 5 milligrams per pound of body weight administered in divided doses at 6 to 12 hour intervals. Therapy should be continued for at least 24 hours after all symptoms have subsided.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 48 FR 30615, July 5, 1983]

§ 522.1680 Oxytocin injection.

(a) *Specifications.* Each milliliter of oxytocin injection contains 20 U.S.P. units of oxytocin.

(b) *Sponsors.* See Nos. 000010, 000856, 000864, 059130, 058639, and 059130 in § 510.600(c) of this chapter.

(c) *Conditions of use*¹—(1) *Amount*—(i) *Obstetrical.* Administer drug intravenously, intramuscularly, or subcutaneously under aseptic conditions as indicated. The following dosages are recommended and may be repeated as conditions require:

	ml	U.S.P. units
Cats	0.25 to 0.5	5 to 10.
Dogs	0.25 to 1.5	5 to 30.
Ewes, Sows	1.5 to 2.5	30 to 50.
Cows, Horses	5.0	100.

(ii) *Milk letdown.* Intravenous administration is desirable. The following dosage is recommended and may be repeated as conditions require:

	ml	U.S.P. units
Cows	0.5 to 1.0	10 to 20.
Sows	0.25 to 1.0	5 to 20.

(2) *Indications for use.* Oxytocin may be used as a uterine contractor to precipitate and accelerate normal parturition and postpartum evacuation of uterine debris. In surgery it may be used postoperatively following cesarean section to facilitate involution and

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bio-equivalency and safety information.

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resistance to the large inflow of blood. It will contract smooth muscle cells of the mammary gland for milk letdown if the udder is in proper physiological state.

(3) *Limitations.* Do not use in dystocia due to abnormal presentation of fetus until correction is accomplished. For prepartum usage, full relaxation of the cervix should be accomplished either naturally or by administration of estrogen prior to oxytocin therapy. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[44 FR 63097, Nov. 2, 1979; 45 FR 1019, Jan. 4, 1980, as amended at 52 FR 18691, May 19, 1987; 52 FR 25212, July 6, 1987; 52 FR 36023, Sept. 25, 1987; 53 FR 32610, Aug. 26, 1988; 53 FR 40728, Oct. 18, 1988; 54 FR 41442, Oct. 10, 1989; 55 FR 8462, Mar. 8, 1990; 56 FR 14642, Apr. 11, 1991, 56 FR 16002, Apr. 19, 1991; 59 FR 31139, June 17, 1994; 62 FR 35076, June 30, 1997; 62 FR 38906, July 21, 1997; 65 FR 45877, July 26, 2000; 66 FR 22117, May 3, 2001]

§ 522.1696 Penicillin G procaine implantation and injectable dosage forms.

§ 522.1696a Penicillin G benzathine and penicillin G procaine sterile suspension.

(a) *Specifications.* Each milliliter of aqueous suspension contains penicillin G benzathine and penicillin G procaine, each equivalent to 150,000 units of penicillin G.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for the conditions of use in paragraph (d) of this section as follows:

(1) Nos. 000008, 000856, 000864, 010515, and 049185 for use as in paragraph (d)(1) of this section.

(2) Nos. 000856 and 049185 for use as in paragraphs (d)(2)(i), (d)(2)(ii)(A), and (d)(2)(iii) of this section.

(3) Nos. 000864, 010515, and 059130 for use as in paragraphs (d)(2)(i), (d)(2)(ii)(B), and (d)(2)(iii) of this section.

(c) *Related tolerances.* See § 556.510 of this chapter.

(d) *Conditions of use*—(1) *Horses, dogs, and beef cattle*—(i) *Amount*—(A) *Beef cattle.* 2 milliliters per 150 pounds of body weight intramuscularly or subcutaneously. Repeat dosage in 48 hours.

(B) *Horses*. 2 milliliters per 150 pounds of body weight intramuscularly. Repeat dosage in 48 hours.

(C) *Dogs*. 1 milliliter per 10 to 25 pounds of body weight intramuscularly or subcutaneously. Repeat dosage in 48 hours.

(ii) *Conditions of use*. Treatment of bacterial infections susceptible to penicillin G.

(iii) *Limitations*. In beef cattle, treatment should be limited to two doses. Not for use in beef cattle within 30 days of slaughter. Do not use in horses intended for food purposes. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Beef cattle*—(i) *Amount*. 2 milliliters per 150 pounds of body weight subcutaneously. Repeat dosage in 48 hours.

(ii) *Conditions of use*. (A) Treatment of bacterial pneumonia (*Streptococcus* spp., *Corynebacterium pyogenes*, *Staphylococcus aureus*); upper respiratory infections such as rhinitis or pharyngitis (*Cpyogenes*); blackleg (*Clostridium chauvoei*).

(B) As in paragraph (d)(2)(ii)(A) of this section; and prophylaxis of bovine shipping fever in 300- to 500-pound beef calves.

(iii) *Limitations*. Limit treatment to two doses. Not for use within 30 days of slaughter.

[66 FR 711, Jan. 4, 2001]

§522.1696b Penicillin G procaine aqueous suspension.

(a) *Specifications*. Each milliliter contains penicillin G procaine equivalent to 300,000 units of penicillin G.

(b) *Sponsors*. See sponsor numbers in §510.600(c) of this chapter as follows:

(1) Nos. 010515, 053501, and 059130 for use as in paragraph (d) of this section.

(2) Nos. 000864 and 055529 for use as in paragraph (d)(2) of this section.

(c) *Related tolerances*. See §556.510 of this chapter.

(d) *Conditions of use*—(1) *Dogs and cats*—(i) *Amount*. 10,000 units per pound body weight daily by intramuscular injection at 24-hour intervals. Continue treatment at least 48 hours after symptoms disappear.

(ii) *Indications for use*. Treatment of infections caused by penicillin-sensitive organisms.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cattle, sheep, swine, and horses*—(i) *Amount*. 3,000 units per pound body weight (1 milliliter per 100 pounds body weight) daily by intramuscular injection.

(A) For Nos. 000864, 010515, 053501, and 059130: Continue treatment at least 48 hours after symptoms disappear.

(B) For No. 055529: Continue treatment at least 1 day after symptoms disappear (usually 2 or 3 days).

(ii) *Indications for use*. Treatment of cattle and sheep for bacterial pneumonia (shipping fever) caused by *Pasteurella multocida*; swine for erysipelas caused by *Erysipelothrix insidiosa*; and horses for strangles caused by *Streptococcus equi*.

(iii) *Limitations*. Not for use in horses intended for food.

(A) For Nos. 000864, 010515, 053501, and 059130: Do not exceed 7 days of treatment in nonlactating dairy and beef cattle, sheep, and swine, or 5 days in lactating cattle. Milk that has been taken during treatment and for 48 hours after the last treatment must not be used for food. Discontinue treatment for the following number of days before slaughter: Nonruminating cattle (calves)—7, all other cattle—4, sheep—8, and swine—6.

(B) For No. 055529: Treatment should not exceed 4 consecutive days. Milk that has been taken during treatment and for 72 hours after the last treatment must not be used for food. Discontinue treatment for the following number of days before slaughter: Cattle—10, sheep—9, and swine—7.

[66 FR 712, Jan. 4, 2001]

§522.1696c Penicillin G procaine in oil.

(a) *Specifications*. Each milliliter contains penicillin G procaine equivalent to 300,000 units of penicillin G.

(b) *Sponsor*. See No. 053501 in §510.600(c) of this chapter.

(c) *National Academy of Sciences/National Research Council (NAS/NRC) status*. The conditions of use were NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by